

**Carette S, Moffet H et al. Intraarticular Corticosteroids, Supervised Physiotherapy, or a Combination of the Two in the Treatment of Adhesive Capsulitis of the Shoulder. Arthritis Rheum 2003;48:829-838.**

Design: Randomized clinical trial

Study question: In patients with adhesive capsulitis, what are the comparative efficacies of treatment with a single steroid injection, a supervised physical therapy (PT) program, a combination of steroid plus PT, and placebo interventions?

Population/sample size/setting:

- 93 patients (55 women, 38 men, mean age 55) treated for adhesive capsulitis at a university rheumatology department in Canada
- Eligible if over 18, symptomatic for less than 1 year, with shoulder pain and limitation of both active and passive glenohumeral ROM of at least 25% in at least 2 directions compared to other shoulder, with score of at least 30 on Shoulder Pain and Disability Index (SPADI)
- Ineligible if capsulitis secondary to another cause such as systemic disease, stroke, or fracture

Main outcome measures:

- Randomized to steroid (40 mg intraarticular triamcinolone) + PT (n=21), steroid alone (n=23), saline + PT (n=26), or saline alone (n=23), all injections with fluoroscopic guidance using foil-wrapped syringes
  - o Patients were divided into “acute” and “chronic” capsulitis depending on five criteria involving pain VAS scores on a 10 point scale
  - o The five criteria were (1) rest pain  $\geq 4$ , (2) rest pain present  $\geq 75\%$  of the time during the day, (3) pain on active shoulder elevation  $\geq 4$ , (4) presence of night pain, and (5) spasm or empty end-feel (pain stopping passive motion before any articular resistance is felt by the examiner) in at least 2 directions of passive motion
  - o “Acute” adhesive capsulitis meant that 3 or more of these criteria were met; “chronic” meant that less than 3 were met
  - o “Acute” patients had PT consisting of TENS followed by mobilization techniques, active ROM exercises, and ice application
  - o “Chronic” patients had PT consisting of ultrasound, active and auto-assisted ROM exercises, isometric exercises, and ice application
- Before randomization, all patients had 3 months of home exercise program, with 10 minutes of exercise twice per day; compliance with this was high
- PT consisted of 4 weeks of thrice weekly one-hour sessions (12 sessions total) under supervision of a physiotherapist
- Baseline, 6 weeks, 3 months, 6 months, and 1 year measurements of SPADI, SF-36, and active + passive shoulder ROM were done by blinded physical therapists; treatment effect defined as group difference in change scores from baseline

- At 6 weeks, both steroid groups had improved more on SPADI than either saline group; there was a clinically (10 point) but not statistically significant advantage for the steroid + PT group over the steroid alone group
- At 6 weeks, all groups had improved on SF-36, with no group differences
- At 6 weeks, all groups had improved ROM; steroid + PT group improved more than the other 3 groups, and the steroid alone group improved more than the saline alone group
- At 3, 6, and 12 months, all groups continued to improve; at 12 months, there were no significant group differences on any outcome measure

Authors' conclusions:

- Single fluoroscopically guided intraarticular injection of triamcinolone combined with simple home exercise program is effective in improving pain and disability in adhesive capsulitis
- Supervised PT plus saline injection did not result in any significant advantage compared with placebo (saline injection only)
- Study limited by failure to recruit patients who met entry criteria; 36 patients per group were planned in order to have 80% power at alpha level of 0.05, but number recruited fell short of this goal

Comments:

- Important requirements for good study design were met; concealment of allocation, blinding, and relevant, long + short term results were reported; baseline imbalances in sex distribution were adjusted for in analysis
- Eligibility for entry included symptoms for less than 1 year; given the natural history of adhesive capsulitis and the wide range of duration of symptoms eligible for entry, it is likely that the population was heterogeneous with respect to stage of disease at the time of entry into study; this could obscure some treatment effects between groups
- Difficulty in recruiting enough eligible patients means that study was underpowered to detect difference between steroid + PT and steroid alone. A clinically important difference could have been missed; the fact that there were 9 patients in the steroid only group and only 2 in the steroid + PT group who did not return for all visits suggests that a combination of PT and steroid has an advantage over steroid alone.
- Two different PT programs were described, which were assigned depending on acuteness of symptoms; no further information was given concerning outcome differences between the two PT programs; there appears to have been no point to making the distinctions between "acute" and "chronic" capsulitis, making the study needlessly complicated but not invalidating the results

Assessment: Adequate for some evidence that a single injection of 40 mg triamcinolone, when added to a brief supervised physiotherapy program, provides greater benefits than a supervised physiotherapy program alone

